



RECEIVED

MAR 12 2002

TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JU10 Rec'd PCT/PTO 27 DEC 2001

PCT

PATENT

Customer No. 22,852

Attorney Docket No. 08593.0001

File

APR

2002

In re Application of:

Gail LEWANDOWSKI et al.

Application No.: 09/914,840

Filed: September 4, 2001

For: APPLICATION OF DNA VECTORS  
FOR THE TREATMENT OF VIRAL  
INFECTION

)  
AU 1635)

424/93.2 )

) Group Art Unit: Unassigned

) Examiner: Unassigned

RECEIVED

MAR 13 2002

Technology Center 2600

Commissioner for Patents and Trademarks  
Washington, DC 20231

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits.

Copies of the listed documents, including any copending patent applications, are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

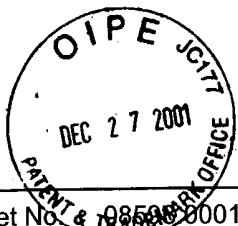
Dated: December 27, 2001

By:

  
Robert A. Pollock  
Reg. No. 43,008

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)



RECEIVED OMB No. 0651-0011

INFORMATION DISCLOSURE CITATION

MAR 15 2002

Atty. Docket No. 08508-0001	Serial No. 09/914,640 TECH CENTER 1600/2900	RECEIVED MAR 13 2002
Applicant Gail LEWANDOWSKI et al.		
Filing Date September 4, 2001	Group: Unassigned	RECEIVED Technology Center 2600 APR 11 2002

U.S. PATENT DOCUMENTS

APR 11 2002

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,672,344	09/30/97	Kelley et al.			
	5,661,033	08/26/97	Ho et al.			
	5,599,691	02/04/97	Roizman			
	5,501,979	03/26/96	Geller et al.			
	5,288,641	02/22/94	Roizman			
	5,059,538	10/22/91	Nozaki et al.			
	4,970,155	11/13/90	Okasinski			

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	0 453 242 A1	10/23/91	EP			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Abdallah et al., "A Powerful Nonviral Vector for <i>In Vivo</i> Gene Transfer into the Adult Mammalian Brain: Polyethylenimine," <i>Human Gene Therapy</i> , Vol. 7, pp. 1947-1954 (1996).
	Arao et al., "Unexpected Correlation in the Sensitivity of 19 Herpes Simplex Virus Strains to Types I and II Interferons," <i>Journal of Interferon and Cytokine Research</i> , Vol. 17, pp. 537-541 (1997).
	Baker et al., "Enhancement of Vaginal Infection in Mice by Herpes Simplex Virus Type II with Progesterone (40156)," <i>Proceedings of Society for Experiment Biology and Medicine</i> , Vol. 158, pp. 131-134 (1978).
	Becker, Y., "HSV-1 Brain Infection by the Olfactory Nerve Route and Virus Latency and Reactivation May Cause Learning and Behavioral Deficiencies and Violence in Children and Adults: A Point of View," <i>Virus Genes</i> , Vol. 10, pp. 217-226 (1995).
	Billue, J.S., "Bell's Palsy: An Update on Idiopathic Facial Paralysis," <i>The Nurse Practitioner</i> , Vol. 22, pp. 88-105 (1995).
	Boletta et al., "Nonviral Gene Delivery to the Rat Kidney with Polyethylenimine," <i>Human Gene Therapy</i> , Vol. 8, pp. 1243-1251 (1997).
	Bouley et al., "Characterization of Herpes Simplex Virus Type-1 Infection and Herpetic Stromal Keratitis Development in IFN- $\gamma$ Knockout Mice," <i>The Journal of Immunology</i> , Vol. 155, pp. 3964-3971 (1995).
	Boussif et al., "A Versatile Vector for Gene and Oligonucleotide Transfer into Cells in Culture and <i>In Vivo</i> : Polyethylenimine," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 92, pp. 7297-7301 (1995).

## INFORMATION DISCLOSURE CITATION

RECEIVED

OMB No. 0651-0011

MAR 15 2002

Atty. Docket No.	08593.0001	Serial No.	09/914,840
Applicant	Gail LEWANDOWSKI et al.		
Filing Date	September 4, 2001	Group:	Unassigned

TECH CENTER 1600 RECEIVED

MAR 13 2002 V31

Technology Center 2600  
Technology Center 2002

TECHNOLOGY CENTER 2002

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>O I P E J C N T</i> <i>DEC 27 2001</i> <i>PATENT &amp; TRADEMARK OFFICE USA</i>	Brooks et al., "Use of the Herpes Amplicon System as a Vehicle for Somatic Gene Transfer," <i>Advanced Drug Delivery Reviews</i> , Vol. 27, pp. 29-39 (1997).
	DeClercq, E., "Acyclic Nucleoside Phosphonates in the Chemotherapy of DNA Virus and Retrovirus Infections," <i>Intervirology</i> , Vol. 40, pp. 295-303 (1997).
	Drugs for Non-HIV Viral Infections, <i>The Medical Letter on Drugs and Therapeutics</i> , edited by Mark Abramowicz, Vol. 39, pp. 69-76 (1997).
	Erlich, K.S., "Management of Herpes Simplex and Varicella-Zoster Virus Infections," <i>The Western Journal of Medicine</i> , Vol. 166, pp. 211-215 (1997).
	Faro, S., "A Review of Famciclovir in the Management of Genital Herpes," <i>Infectious Diseases in Obstetrics and Gynecology</i> , Vol. 6, pp. 38-43 (1998).
	Feduchi et al., "Human Gamma Interferon and Tumor Necrosis Factor Exert a Synergistic Blockade on the Replication of Herpes Simplex Virus," <i>Journal of Virology</i> , Vol. 63, pp. 1354-1359 (1989).
	Feduchi et al., "Mechanism of Inhibition of HSV-1 Replication by Tumor Necrosis Factor and Interferon $\gamma$ ," <i>Virology</i> , Vol. 180, pp. 822-825 (1991).
	Fotaki et al., "Tetracycline-Responsive Gene Expression in Mouse Brain After Amplicon-Mediated Gene Transfer," <i>Gene Therapy</i> , Vol. 4, pp. 901-908 (1997).
	Freeman et al., "Failure of Topical Acyclovir in Ointment to Penetrate Human Skin," <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 29, pp. 730-732 (1986).
	Frenkel et al., "The Herpes Simplex Virus Amplicon--A Versatile Defective Virus Vector," <i>Therapy</i> , Vol. 1, pp. S40-S46 (1994).
	Geiger et al., "Interferon- $\gamma$ Protects Against Herpes Simplex Virus Type 1-Mediated Neuronal Death," <i>Virology</i> , Vol. 238, pp. 189-197 (1997).
	Geller et al., "Long-Term Increases in Neurotransmitter Release From Neuronal Cells Expressing a Constitutively Active Adenylate Cyclase From a Herpes Simplex Virus Type I Vector," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 90, pp. 7603-7607 (1993).
	Gieroba et al., "Herpes Simplex Virus Induces Fos Expression in Rat Brainstem Neurons," <i>Brain Research</i> , Vol. 675, pp. 329-332 (1995).
	Goldman, C.K., "In Vitro and In Vivo Gene Delivery Mediated by a Synthetic Polycationic Amino Polymer," <i>Nature Biotechnology</i> , Vol. 15, pp. 462-466 (1997).
	Gresser et al., "Role of Interferon in the Pathogenesis of Virus Diseases in Mice as Demonstrated by the Use of Anti-Interferon Serum," <i>The Journal of Experimental Medicine</i> , Vol. 144, pp. 1316-1323 (1976).
	Hamuy et al., "Treatment of Herpes Simplex Virus Infections wth Topical Antiviral Agents," <i>Eur. J. Dermatol.</i> , Vol. 8, pp. 310-319 (1998).

RECEIVED  
INFORMATION DISCLOSURE CITATION

OMB No. 0651-0011

MAR 1 2002

Atty. Docket No.	08593.0001	Serial No.	09/914,840
Applicant	Gail LEWANDOWSKI et al.	RECEIVED TECH CENTER 1600/2900	MAR 13 2002
Filing Date	September 4, 2001	Group:	Unassigned Technology Center 2600

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>O I P E SCIT</i>	Hargrave et al., "Movement Disorders in Association with Herpes Simplex Virus Encephalitis in Children: A Review," <i>Developmental Medicine and Child Neurology</i> , Vol. 40, pp. 640-642 (1998).
<i>DEC 27 2001</i>	Ho, D.Y., "Amplicon-Based Herpes Simplex Virus Vectors," <i>Methods in Cell Biology</i> , Vol. 43, pp. 191-210 (1994). <i>REC'D MAR 11 2002</i>
<i>PATENT &amp; TRADEMARK OFFICE</i>	Itzhaki et al., "HSV-1 and Risk of Alzheimer's Disease," <i>The Lancet</i> , Vol. 352, pp. 238-(1998). <i>REC'D MAR 11 2002</i>
	Johnston et al., "HSV/AAV Hybrid Amplicon Vectors Extend Transgene Expression in Human Glioma Cells," <i>Human Gene Therapy</i> , Vol. 8, pp. 359-370 (1997). <i>REC'D MAR 11 2002</i>
	Kimura et al., "Herpes Simplex Encephalitis with Transient Global Amnesia as an Early Sign," <i>Internal Medicine</i> , Vol. 34, pp. 131-133 (1995).
	Komatsu et al., "Interferon-γ Induced Type I Nitric Oxide Synthase Activity Inhibits Viral Replication in Neurons," <i>Journal of Neuroimmunology</i> , Vol. 68, pp. 101-108 (1996).
	Kumano et al., "Protection Against Herpes Simplex Virus Infection in Mice by Recombinant Murine Interferon-β in Combination with Antibody," <i>Antiviral Research</i> , Vol. 7, pp. 289-301 (1987).
	Levitz, R. E., "Herpes Simplex Encephalitis: A Review," <i>Heart &amp; Lung</i> , Vol. 27, pp. 209-212(1998).
	Lewandowski et al., "Interference with Major Histocompatibility Complex Class II-Restricted Antigen Presentation in the Brain by Herpes Simplex Virus Type I: A Possible Mechanism of Evasion of the Immune Response," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 90, pp. 2005-2009 (1993).
	Lewandowski, G. et al., "Alteration of Intracerebral Cytokine Production in Mice Infected with Herpes Simplex Virus Types I and 2," <i>Journal of Neuroimmunology</i> , 55, pp. 23-34 (1994).
	Lewandowski, G. et al., "Evidence for Deficiencies in Intracerebral Cytokine Production, Adhesion Molecule Induction, and T Cell Recruitment in Herpes Simplex Virus Type 2 Infected Mice," <i>Journal of Neuroimmunology</i> , Vol. 81, pp. 58-65 (1998).
	Lewandowski, G., "Immunohistochemical Examination of Intracerebral T Cell Recruitment and Adhesion Molecule Induction in Herpes Simplex Virus-Infected Mice," <i>Brain, Behavior, and Immunity</i> , Vol. 11, pp. 264-272 (1997).
	Lin et al., "Neurotropic Viruses and Alzheimer Disease," <i>Molecular and Chemical Neuropathology</i> , Vol. 28, pp. 135-141 (1996).
	Manos, J., "DNA Viruses I: Herpesviruses," in <i>Microbiology and Infectious Disease</i> , pp. 277-283, 3 <sup>rd</sup> Edition.
	Milligan et al., "Interferon-γ Enhances Resolution of Herpes Simplex Virus Type 2 Infection of the Murine Genital Tract," <i>Virology</i> , 229, pp. 259-268 (1997).
	Parr et al., "A Mouse Model for Studies of Mucosal Immunity to Vaginal Infection by Herpes Simplex Virus Type 2," <i>Laboratory Investigation</i> , Vol. 70, pp. 369-380 (1994).
	Reusser et al., "Herpesvirus Resistance to Antiviral Drugs: a Review of the Mechanisms, Clinical Importance and Therapeutic Options," <i>Journal of Hospital Infection</i> , Vol. 33, pp. 235-248 (1996).
	Rinaldo et al., "Cell-Mediated Immunity and Immunosuppression in Herpes Simplex Virus Infection," <i>Immunodeficiency</i> , Vol. 5, pp. 33-90 (1993).

RECEIVED

OMB No. 0651-0011

## INFORMATION DISCLOSURE CITATION

MAR 1 2002

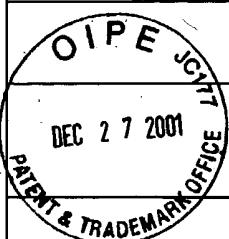
TECH CENTER 1600/2900

Atty. Docket No.	08593.0001	Serial No.	09/914,840
Applicant	Gail LEWANDOWSKI et al.		
Filing Date	September 4, 2001	Group:	Unassigned

RECEIVED

MAR 13 2002

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Technology Center 2600

 <i>DEC 27 2001</i>	Roizmann et al., "Herpes Simplex Viruses and Their Replication," <i>Fundamental Virology</i> , 3 <sup>rd</sup> Ed., Edited by B.N. Fields, et al., pp. 1043-1105 (1996).
	Schmitt et al., "Antiviral Effects of Recombinant Human Tumor Necrosis Factor-Alpha in Combination with Natural Interferon-Beta in Mice Infected with Herpes Simplex Virus Type I," <i>Antiviral Research</i> , Vol. 19, pp. 347-352 (1992). <i>17/11/2002</i>
	Senba et al., "Stress-Induced Expression of Immediate Early Genes in the Brain and Peripheral Organs of the Rat," <i>Neuroscience Research</i> , Vol. 29, pp. 183-207 (1997). <i>17/11/2002</i>
	Sharp et al., "Alterations in Gene Expression as an Index of Neuronal Injury: Heat Shock and the Immediate Early Gene Response," <i>NeuroToxicology</i> , Vol. 15, pp. 51-60 (1994).
	Slack et al., "Viral Vectors for Modulating Gene Expression in Neurons," <i>Current Opinion in Neurobiology</i> , Vol. 6, pp. 576-583 (1996).
	Smith et al., "Control of Acute Cutaneous Herpes Simplex Virus Infection: T Cell-Mediated Viral Clearance is Dependent Upon Interferon-γ (IFN-γ)," <i>Virology</i> , Vol. 202, pp. 76-88 (1994).
	Spruance et al., "Early Application of Topical 15% Idoxuridine in Dimethyl Sulfoxide Shortens the Course of Herpes Simplex Labialis: A Multicenter Placebo-Controlled Trial," <i>Journal of Infectious Diseases</i> , Vol. 161, pp. 191-197 (1990).
	Spruance et al., "Treatment of Herpes Simplex Labialis with Topical Acyclovir in Polyethylene Glycol," <i>The Journal of Infectious Diseases</i> , Vol. 146, pp. 85-90 (1982).
	Spruance, S.L., "Treatment of Herpes Simplex Labialis," <i>Clinical Use of Antiviral Drugs</i> , Edited by Dr. E. De Clercq (1988).
	Stanberry, L.R., "Pathogenesis of Herpes Simplex Virus Infection and Animal Models for Its Study," <i>Current Topics in Microbiology and Immunology</i> , Vol. 179, pp. 15-30 (1992).
	Svennerholm et al., "Herpes Simplex Virus Infection of the Rat Sensory Neuron Effects of Interferon on Cultured Cells," <i>Arch Virol.</i> , Vol. 104, pp. 153-156 (1989).
	Syed et al., "Human Leukocyte Interferon-α in a Hydrophilic Cream Versus in a Gel for the Treatment of Genital Herpes in Males: A Placebo-Controlled, Double-Blind, Comparative Study," <i>The Journal of Dermatology</i> , Vol. 24, pp. 564-568 (1997).
	Tung et al., "Rapid Production of Interleukin-2-Secreting Tumor Cells by Herpes Simplex Virus-Mediated Gene Transfer: Implications for Autologous Vaccine Production," <i>Human Gene Therapy</i> , Vol. 7, pp. 2217-2224 (1996).
	Tyrrell, R.M., "UV Activation of Mammalian Stress Proteins," <i>Stress-Inducible Cellular Responses</i> , Edited by U. Feige et al. (1996).
	Vilcek et al., "Interferons and Other Cytokines," <i>Fundamental Virology</i> , 3 <sup>rd</sup> Ed., Edited by D.M. Fields et al., pp. 341-365 (1996).
	Whitton et al., "Immune Response to Viruses," <i>Fundamental Virology</i> , 3 <sup>rd</sup> Ed., Edited by B.N. Fields, et al., pp. 311-339 (1996).

RECEIVED  
INFORMATION DISCLOSURE CITATION

OMB No. 0651-0011

Atty. Docket No.	08593.0001	Serial No.	MAR 13 2002 09/914,840	RECEIVED
Applicant	Gail LEWANDOWSKI et al.	TECH CENTER 1600/2900		MAR 13 2002
Filing Date	September 4, 2001	Group:	Unassigned	Technology Center 2600

*O I P E*  
*DEC 21 2001*  
*PATENT & TRADEMARK OFFICE*

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Wilson et al., "Dense Amnesia in a Professional Musician Following Herpes Simplex Virus Encephalitis," <i>Journal of Clinical and Experimental Neuropsychology</i> , Edited by B.N. Fields, et al., Vol. 17, pp. 668-681 (1995). <i>TECH CENTER RC700</i> MAR 13 2002
	Wutzler, P., "Antiviral Therapy of Herpes Simplex and Varicella-zoster Virus Infections," <i>Intervirology</i> , Vol. 40, pp. 343-356 (1997). <i>TECH CENTER RC700</i>
	Yamada et al., "Effect of Recombinant Mouse Interferon-β on Acute and Latent Herpes Simplex Infection in Mice," <i>Arch Virol.</i> , Vol. 99, pp. 101-109 (1988).
	Grant Application of Virion Systems, Inc., "Viral Disease/Topical DNA Therapy/Herpesvirus/Latency, Solicitation No. PHS 98-2.
	Grant Application of Virion Systems, Inc., "Mental Health Disorders/Neuron Control of Viral Latency, Solicitation No. PA-93-009.

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce